INTERVIEW SUMMARY

Applicants would like to thank Examiner Portner for conducting an in-person interview for this case on February 28, 2008. Applicants discussed the claims of record, the prior art of record and the outstanding rejections. Applicants agreed to submit amendments to clarify the claims and a Request for Continued Examination.

REMARKS/ARGUMENTS

Responsive to the Office Action dated February 22, 2007, Applicants respectfully request consideration of the following remarks and reconsideration of the application. Claims 28 and 29 have previously been canceled. Claims 1-3, 6-22, 24 and 27 were pending and under consideration. Claims 13-14, 18-19 and 21-22 have been canceled herein. Claims 1, 3, 8, 12, 15 17, 20 and 24 have been amended. Applicants submit that no new matter has been added by way of these amendments. Each of these claims is believed to be in condition for allowance and such favorable action is requested.

Objections

Claims 13 and 14 have been objected to for informalities. Claim 13 and 14 have been cancelled and the informalities have been corrected in claim 12 as amended. As such, Applicants request withdrawal of the objection to these claims.

§112 Rejections

A) Rejections Based on 112, Second Paragraph

Claims 13-14, 17-18, and 21-23 have been rejected for being incomplete for omitting essential elements. Applicants have amended the claims 12, 17 and 20 to include the steps for creating a readable sample. Applicants have canceled claims 13-14, 18-19, and 21-22. Claim 23 had been previously canceled. As such, Applicants request withdrawal of these rejections.

Claim 8 has been rejected as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Claim 8 has been amended to recite "immunoassays utilizing antibodies for capturing fragments" rather than "or capturing fragments." Applicants submit that claim 8, as amended, is definite and request withdrawal of the rejection.

Claims 14, 19 and 22 have been rejected as being indefinite. Claims 14, 19 and 22 have been canceled. As such, Applicants request withdrawal of the §112 rejection of these claims.

Claim 3 has been rejected as having insufficient antecedent basis for reciting a "diagnosis of irritable bowel syndrome." Claim 3 has been amended to depend directly from claim 1 rather than 2. As such, Applicants submit that there is sufficient antecedent basis and request withdrawal of the rejection of this claim.

Claim 23 has been rejected for reciting the limitation "an enzyme linked antibody bound" sample. Applicants have canceled claim 23 and amended claim 20 to include enzyme-linked polyvalent antibodies and as such request withdrawal of the rejection.

B) Rejections Based on 112, First Paragraph

Claims 1-3, 6-22, 24 and 27 stand rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. Applicants have cancelled the phrase "other than a breast-fed infant" from independent claims 1 and 24. As such, Applicants request withdrawal of this rejection.

§102 Rejections

A.) Applicable Authority

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdeggal Brothers v. Union Oil Co. of California*, 814 F.2d 628, 631 2 USPQ 2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the . . . claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 2 USPQ 2d 1913, 1920 (Fed. Cir. 1989). *See also*, MPEP §2131.

B.) Anticipation Rejections Based on the Guerrant Reference (US Pat. 5,124,252)

Claims 1, 8-12, 13 and 24 have been rejected as being anticipated by Guerrant et al, (US Pat. 5,124,252) (hereinafter the "Guerrant reference.") As the Guerrant reference fails to describe, either expressly or inherently, each and every element as set forth in the rejected claim, Applicants respectfully traverse these rejections.

Claim 1, as amended, is directed to a method for testing a fecal sample from a person for diagnosis. The method comprises

Claim 24, as amended, recites a method for distinguishing inflammatory bowel disease from irritable bowel syndrome and for differentiating ulcerative colitis from Crohn's disease. The method comprises

Claims 1 and 24 include the steps of determining whether a fecal sample with an elevated level of lactoferrin has elevated levels of ASCA and ANCA. The Guerrant reference discloses only the method of obtaining a fecal sample from a person and determining whether lactoferrin is present in the sample; it does not discuss determining whether a fecal sample contains an elevated level of ASCA and ANCA. As such, Guerrant reference does not anticipate the claimed invention, and Applicants request withdrawal of the 103(a) rejection of claims 1 and 24. As claims 8-12, and 13, as amended, depend directly or indirectly from claim 1, Applicants request withdrawal of the rejection of these claims as well.

§ 103(a) Rejections

A) Title 35 U.S.C. § 103(a) declares, a patent shall not issue when "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." The Supreme Court in *Graham v. John Deere* counseled that an obviousness determination is made by identifying: the scope and content of the prior art; the level of ordinary skill in the prior art; the

differences between the claimed invention and prior art references; and secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1 (1966).

To support a finding of obviousness, the initial burden is on the Office to apply the framework outlined in *Graham* and to provide some "articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR Int'l Co. v. Teleflex Inc.,* 127 S. Ct. 1727 at 1741, 82 USPQ2d at 1396 (quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006) with approval)." *See also* MPEP § 2142. "[R]ejections on obviousness cannot be sustained with mere conclusory statements." *Id.* Thus, in order to establish a *prima facie* case of obviousness the Office must provide "a clear articulation of the reason(s) why the claimed invention would have been obvious" based on factual findings made while conducting the *Graham* factual inquires. *See* MPEP § 2143. The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicitly. *Id.*

B.) Obviousness Rejection Based on the Nielson Reference (Nielson et al., *The American Journal of Gastroenterology*, Vol. 95, No. 2, 359-367, 2000) in View of the Targan Reference (*Journal of Immunology*, 1995, Vol. 155, Issue 6, 3262-3267, 1995) and the Fine (2) Reference (PG – Pub 2001/0036639A1, filing date March 2, 2001).

Claims 1-10 and 24-26 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Nielson et al. (*The American Journal of Gastroenterology*, Vol. 95, No. 2, 359-367, 2000) (hereinafter the "Nielson reference") in view of Targan et al. (*Journal of Immunology*, 1995, Vol. 155, Issue 6, 3262-3267, 1995) (hereinafter the "Targan reference") and Fine (PG – Pub 2001/0036639A1, filing date March 2, 2001) (hereinafter "the Fine (2) reference"). Applicants submit claimed invention not obvious because of the significant differences between the cited references and the claimed invention.

Claim 1, as amended, is directed to a method for testing a fecal sample from a person for diagnosis. The method comprises obtaining a fecal sample from a person presenting with symptoms common to inflammatory bowel disease and irritable bowel syndrome. The sample is measured for an elevated level of lactoferrin. The sample having elevated lactoferrin is selected for further analysis. The selected sample is measured for an elevated level of anti-*Saccharomyces cerevisiae* antibodies (ASCA) and for an elevated level of anti-neutrophil cytoplasmic antibodies (ANCA). The method comprises diagnosing Crohn's disease for the person having a sample with an elevated level of anti-*Saccharomyces cerevisiae* antibodies; and diagnosing ulcerative colitis for the person having a sample with an elevated level of anti-neutrophil cytoplasmic antibodies.

Claim 24, as amended, is directed to a method for distinguishing inflammatory bowel disease from irritable bowel syndrome and for differentiating ulcerative colitis from Crohn's disease. The method comprises obtaining a fecal sample from a person presenting with symptoms common to inflammatory bowel disease and irritable bowel syndrome. The sample is measured for an elevated or non-elevated level of lactoferrin. The method comprises diagnosing the person having a non-elevated level of lactoferrin with irritable bowel syndrome. The method further comprises selecting the sample having an elevated level of lactoferrin for further measurements. The selected sample having an elevated level of lactoferrin is measured for an elevated level of anti-*Saccharomyces cerevisiae* antibodies (ASCA) and an elevated level of lactoferrin for an elevated level of anti-neutrophil cytoplasmic antibodies (ANCA). The method differentiates between a diagnosis of Crohn's disease for the person having a sample with an elevated level of anti-*Saccharomyces cerevisiae* antibodies and a diagnosis of ulcerative colitis for the person having a sample with an elevated level of anti-neutrophil cytoplasmic antibodies.

Applicants submit that Nielsen in view of Targan in view of Fine neither teaches nor suggests diagnosing Crohn's disease for the person having a sample with an elevated level of anti-*Saccharomyces cerevisiae* antibodies and diagnosing ulcerative colitis for the person having a sample with an elevated level of anti-neutrophil cytoplasmic antibodies.

Nielsen discloses testing for ASCA and ANCA in serum. (See Nielsen, Page 361). Nielsen does not teach testing a fecal sample for an elevated level of ANCA or ASCA. Furthermore, Nielson does not teach diagnosing Crohn's disease for a person that has an elevated level of ASCA in a fecal sample or diagnosing ulcerative colitis for a person that has an elevated level of ANCA in a fecal sample. There is no discussion of what constitutes an elevated level of ASCA or ANCA in a fecal sample in Nielson.

Targan does not cure this deficiency. Like Nielsen, Targan determines the presence of ANCA or ASCA is determined in a serum sample. (See Targan, Page 3262). Targan does not teach diagnosing a person with an elevated level of ASCA with Crohn's disease. Furthermore, there is no teaching or suggestion in Targan what an elevated level of ANCA in a fecal sample is. Targan does not teach that ANCA crosses through the intestinal wall from the serum in such an amount that a diagnosis of ulcerative for a person having an elevated level of ANCA in a fecal sample.

Likewise, Fine does not teach or suggest diagnosing ulcerative colitis for a person having a sample with an elevated level of ANCA. Rather, Fine teaches a method for diagnosing food sensitivities. Fine does not teach or suggest diagnosing Crohn's disease if a fecal sample contains an elevated level of anti-*saccharomyces cerevisiae* antibodies of Crohn's disease. Rather, Fine teaches a method for diagnosing food sensitivities. Crohn's disease is not a food sensitivity to *Saccharomyces cerevesiae*. Fine does not teach or suggest that an elevated level ASCA in fecal sample can be used to diagnose Crohn's disease.

Furthermore, it would not be obvious to one of skill in the art to combine the cited references to make the claimed invention. Just because a marker may be contained in some level in a fecal sample, does not make it obvious that it would occur in an amount that is measurable in order to diagnose a particular disease state, e.g., diagnosing Crohn's disease for a person having a fecal sample with elevated ASCA. Furthermore, just because a cut-off level can be determined in serum to diagnose a disease does not make it applicable to a fecal sample. Human serum varies greatly from human feces. One of skill in the art can appreciate that human feces varies greatly in consistency and make-up based human diet, health and lifestyle much more so than human serum varies based on these factors. As such, it would not have been obvious to one of skill in the art that a cut-off level to define an elevated level of a marker, such as ASCA, actually could be determined in feces based on results of testing done for serological markers.

Furthermore, the method of claim 24 includes distinguishing between IBD and IBS. When a patient presents with symptoms common to IBD and IBS, it is difficult to distinguish between the two conditions. Claim 24 relates to diagnosing IBS when a patient presents with symptoms common to IBD and IBS if the level of fecal lactoferrin is not elevated for the patient. The prior art does not teach this. Specifically, the Nielson, Targan and Fine do not teach measuring the level of lactoferrin in patients with IBS. It was unknown whether patients with IBS had elevated levels of lactoferrin. More specifically, while Nielson teaches that fecal lactoferrin may be utilized as a marker for disease activity in IBD, the Nielson is silent as to whether patients with IBS have elevated levels of lactoferrin.

Targan and Fine do not cure this deficiency. Targan and Fine also fail to teach or suggest diagnosing IBS when a person presents with symptoms common to IBD and IBS if the level of fecal lactoferrin is not elevated for the patient. Targan determines the presence of ANCA in a serum sample and does not discuss determining the level of lactoferrin in a fecal

sample. (See Targan, Page 3262). Fine teaches a method for diagnosing food sensitivities and does not discuss determining the level of lactoferrin in a fecal sample.

Applicants submit that Nielsen in view of Targan in view of Fine neither teaches nor suggests all the claim limitations of independent claims 1 and 24 and as such request withdrawal of the 103(a) rejection of these claims. As the remaining claims depend from independent claims 1 and 24, Applicants request withdrawal of the rejection of these claims as well.

Double Patenting

Claims 1, 3 11-16 and 24 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 of copending Application No. 2204/0033537. Applicants request that this rejection be held in abeyance until such time as subject matter is deemed allowable.

Claims 1, 3, 11-13, 14-16 and 24 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 7,192,724. Applicants request that this rejection be held in abeyance until such time as subject matter is deemed allowable.

Conclusion

As such, the present application is believed to be in condition for allowance, and Applicants request that a timely notice of allowance be issued for this case. Should any unresolved issues remain in the case, please feel free to contact the undersigned at the phone number listed below.

The Commissioner is hereby authorized to charge any amount required to Deposit Account No. 19-2112, referencing attorney docket number TLAB.100292.

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Respectfully submitted,

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